

Sub
B2 C1

12. (Twice Amended) A composition comprising a dimethylglycine component and at least one *Perna canaliculus* component, both in a non-injectable form for administration.

Sub
B2 C2

15. (Twice Amended) A kit comprising a dimethylglycine formulation in a non-injectable form and a *Perna canaliculus* formulation in a non-injectable form, wherein the *Perna canaliculus* formulation comprises at least one *Perna canaliculus* component.

Add the following new claims:

- 20. The composition of claim 12, wherein the composition is in a form suitable for oral administration.

B3 21. The kit of claim 15, wherein both the dimethylglycine formulation and the *Perna canaliculus* formulation are in a form suitable for oral administration.

22. A method for treating lupus erythmatosus, which comprises administering to a patient in need of such treatment an effective amount of a composition according to claim 12.

23. The method of claim 22, wherein the composition is administered orally.

24. The method of claim 22, wherein the amount of dimethylglycine component administered is from 1 to 500 mg/kg/day and the amount of at least one *Perna canaliculus* component administered is from 1 to 500 mg/kg/day.

25. The method of claim 22, wherein the amount of dimethylglycine component administered is from 10 to 100 mg/kg/day and the amount of at least one *Perna canaliculus* component administered is from 10 to 100 mg/kg/day.

26. A method for treating lupus erythmatosus, which comprises administering to a patient in need of such treatment effective amounts of a dimethylglycine formulation and a *Perna canaliculus* formulation from a kit according to claim 15.

27. The method of claim 26, wherein the dimethylglycine formulation and the *Perna canaliculus* formulation are administered orally.

b3 28. The method of claim 26, wherein the amount of dimethylglycine administered is from 1 to 500 mg/kg/day and the amount of at least one *Perna canaliculus* component administered is from 1 to 500 mg/kg/day.

29. The method of claim 26, wherein the amount of dimethylglycine administered is from 10 to 100 mg/kg/day and the amount of at least one *Perna canaliculus* component administered is from 10 to 100 mg/kg/day.

30. A method for modulating the immune response of a patient to decrease the serum levels of il-6, decrease the serum levels of il-10, increase the serum levels of TNF- α and decrease the concentration of CD8⁺ lymphocytes in the blood which comprises administering to a patient in need of such treatment an effective amount of a composition according to claim 12.

31. A method for modulating the immune response of a patient to decrease the serum levels of il-6, decrease the serum levels of il-10, increase the serum levels of TNF- α and decrease the concentration of CD8⁺ lymphocytes in the blood which comprises administering to a patient in need of such treatment effective amounts of a dimethylglycine formulation and a *Perna canaliculus* formulation from a kit according to claim 15.

32. The method of claim 30, wherein the amount of dimethylglycine component administered is from 1 to 500 mg/kg/day and the amount of at least one *Perna canaliculus* component administered is from 1 to 500 mg/kg/day.

33. The method of claim 30, wherein the amount of dimethylglycine component administered is from 10 to 100 mg/kg/day and the amount of at least one *Perna canaliculus* component administered is from 10 to 100 mg/kg/day.

34. The method of claim 31, wherein the amount of dimethylglycine administered is from 1 to 500 mg/kg/day and the amount of at least one *Perna canaliculus* component administered is from 1 to 500 mg/kg/day.

35. The method of claim 31, wherein the amount of dimethylglycine administered is from 10 to 100 mg/kg/day and the amount of at least one *Perna canaliculus* component administered is from 10 to 100 mg/kg/day.

36. The method of claim 30, wherein the composition is administered orally.

37. The method of claim ~~31~~, wherein the dimethylglycine formulation and the *Perna canaliculus* formulation are administered orally.

38. The composition of claim 12, wherein the *Perna canaliculus* component is provided as unrefined whole *Perna canaliculus* mussel.

b3 39. The kit of claim 15, wherein the *Perna canaliculus* formulation is provided as unrefined whole *Perna canaliculus* mussel.

40. The composition of claim 12, wherein the *Perna canaliculus* component is provided as an extract of at least one therapeutically active component of *Perna canaliculus* mussel.

41. The kit of claim 15, wherein the *Perna canaliculus* formulation is provided as an extract of at least one therapeutically active component of *Perna canaliculus* mussel. —.